

Applicant : Anthony J.F. D'Apice et al.  
Serial No. : 08/984,900  
Filed : December 4, 1997  
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Attorney's Docket No.: 06868-005002

### REMARKS

#### Status of the claims

Claims 1-3, 46-51, 67, and 70-77 are pending and under consideration in this application. Claims 1-3, 46-50, 67, and 70-73 are allowed. Claims 51 and 74-77 stand rejected.

#### 35 U.S.C. §112, first paragraph, rejection

Claims 51 and 74-77 stand rejected on the grounds that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

From the comments on page 2, line 12, to page 6, line 12, of the Office Action, Applicants understand the Examiner's position to be that claims 51 and 74-77 read on *in vivo* and *in vitro* methods of generating a porcine cell comprising at least one inactivated  $\alpha$ -1,3 galactosyltransferase gene but that, because the "specification fails to provide adequate guidance and evidence for producing a transgenic animal, such as a transgenic porcine, having [a] disrupted  $\alpha$ -1-3 GT gene in its genome" (Office Action, page 3, lines 14-15), *in vivo* methods are not enabled by the specification. Applicants strongly disagree with this position.

First, it is clear that the specification provides the requisite "guidance and evidence" for producing, at least, a transgenic mouse having [a] disrupted  $\alpha$ -1-3 GT gene in its genome (see, e.g., Examples 9 and 13-15 in the specification and claims 5-13 of U.S. Patent No. 5,849,991, issued on December 15, 1998, from U.S. Application Serial No. 08/378,617 of which the instant application is a divisional). Moreover, Applicants respectfully submit that *in vivo* porcine cells having a disrupted  $\alpha$ -1-3 GT gene are enabled by the specification. Thus, for example, subsequent to the priority date of the instant application, others have created pigs with functionally inactivated  $\alpha$ -1,3-galactosyltransferase genes. All the cells of such pigs comprise a disrupted  $\alpha$ -1,3-galactosyltransferase. Nevertheless, in order to expedite prosecution of the instant application, Applicants have limited claim 51 (and thus also dependant claims 74-77) to an *in vitro* method. No new matter is added by this amendment.

In light of the above considerations, Applicants request that the rejections under 35 U.S.C. §112, first paragraph, be withdrawn.



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Information Disclosure Statement (IDS)

On page 6, lines 13-16, of the Office Action, the Examiner indicated that only "Exhibit NJD-1" cited in the IDS submitted September 30, 2002, had been received by the U.S. Patent and Trademark Office. However, subsequently, in a telephone conversation with Applicants' undersigned representative, the Examiner stated that he had located all the materials cited in the IDS. In the telephone conversation, Applicants' undersigned representative agreed that the materials submitted in the IDS should not be cited in the issued patent. Nevertheless, Applicants respectfully request that the Examiner provide a statement or checked off Forms 1449 indicating that all the materials have been considered by the U.S. Patent and Trademark Office.